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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,386	08/27/2001	Ton Logtenberg	2183-4514.1US	4365

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EXAMINER	
WESSENDORF, TERESA D	
ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/940,386	LOGTENBERG ET AL.	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32,35 and 37-45* is/are pending in the application.

4a) Of the above claim(s) *1-17,29-32,35 and 37-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election of Group VI claims 18-28 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicants request to recombine Group VII to the elected species. Applicants state that combining these groups would not present undue burden to the examiner. This is not found persuasive because Group VII contains additional components not present in Group VI. Because the search for prior art is not limited to patent searches but covers scientific literatures, as well, which are not co-extensive with each other, an undue burden of examination will be involved.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-17, 29-32, 35, 37-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse.

Applicants' election of the species antibody is noted.

Status of Claims

Claims 1-32, 35, 37-45 are pending in the application.

Claims 33-34, 36 and 46-49 have been cancelled.

Claims 1-17, 29-32, 35, 37-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention

Claims 18-28 are under examination.

Drawings

The drawings are objected to because Fig. 5 does not contain Seq. ID. Nos. for the sequences contained therein. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities:

A. The statement under 1.821 that the paper copy and CRF is "believed" to be identical does not comply with requirement

of positive recitation that the paper and CRF copies are "identical" (and not believed to be identical).

Appropriate correction is required.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors (grammatical, idiomatic and typographical). Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 18 is indefinite as to the binding molecule produced by anyone of the claimed processes of claims 1-16. The claimed process does not recite for a method of producing. It is unclear as to the identifying characteristics of said molecules, since the molecule depends on different methods. There are no

identifying characteristics of the molecule to fingerprint the binding molecule.

B. Claim 22 is unclear as to the functional limitation of the binding molecule "capable of distinguishing a subset of CD46 comprising cells".

C. Claim 27 is indefinite as to what constitutes a "part" of the binding molecule since the structure of the binding molecule is not recited.

Double Patenting

Claims 18-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 8 of U.S. Patent No. 6,265,150 ('150 Patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed binding molecule is similar, if not the same as the antibody of the '150 Patent except produced by a different process. It is well-settled that where the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See In re Ludtke, supra. Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie

obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same as is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. See In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972); In re Best 195 USPQ 430 (CCPA 1977).

[It is requested that applicants disclose other copending applications that might be related to the instant applications.]

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 18-24 and 26-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Hofman et al (Breast Cancer Research and

Treatment, abstract only) or applicants' disclosure of known prior art or under 102(a) over de Vries as disclosed in the specification.

Hofman discloses a monoclonal antibody that detects or binds the protein CD46. Therefore, the binding molecule, antibody of Hofman appears the same as the broad claimed binding molecule except produced by different process. It is well-settled that where the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See In re Ludtke, supra. Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same as is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. See In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972); In re Best 195 USPQ 430 (CCPA 1977).

Applicants state at page 37 of the instant disclosure that ".....phage antibody display in combination with flow cytometry was used to isolate human scFv antibody fragments that bind to malignant plasma cells. Details of this method have been

described elsewhere **(De Kruif et al. 1995a and 1995b)**. The preparation of cell suspensions from blood, tonsil, spleen and bone marrow from healthy individuals and multiple myeloma patients is described in **Van der Vuurst de Vries and Logtenberg** (2000). The heterogeneous mixture of mononuclear cells of a patient with Multiple Myeloma was mixed with a phage display library of human scFv fragments, made essentially as described by De Kruif et al. (1995a and 1995b).....Phage antibodies that bound to malignant plasma cells in the bone marrow of patients with Multiple Myeloma and that showed little staining (as performed by De Kruif et al. 1995a) of hematopoietic cells in other lymphoid organs were selected....." (Emphasis added.) Accordingly, the broad claimed binding molecule is fully met by the binding molecule cited in the references disclosed in the instant specification.

Claims 18-22, 26-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Carter et al (2003/0219434).

Carter discloses at [0040] an antibody which is "directed against" or which "specifically binds to" an antigen of interest, e.g. DAF antigen, is one capable of binding that antigen with sufficient affinity such that the antibody is useful as a therapeutic agent in targeting the antigen. The antigen here is

normally DAF as it exists in a patient to be treated with the antibody (especially the antigen expressed by tumor cells in the patient). Notwithstanding this, various forms of DAF (e.g. native, recombinant, and synthetic DAF, including DAF variants and fragments) may be used to generate or raise the antibody. Carter discloses at [0008] that Decay Accelerating Factor (DAF), is a GPI-anchored protein that acts together with two other GPI-anchored proteins, CD46 and CD59, in protecting host cells from complement-mediated cell lysis. DAF is expressed at widely varying levels on tumor cell lines and its overexpression correlates with enhanced resistance to complement-mediated cell lysis in vitro. DAF overexpression has been observed on a variety of human tumor tissues including 6/9 lung adenocarcinomas and 2/7 lung squamous cell carcinomas. Regarding normal lung tissue, DAF has been detected by immunohistochemistry on the alveolar epithelium, interstitium and endothelium as well as the bronchial epithelium, glands and ducts plus blood vessels. Accordingly, the specific antibody of Carter meets the broad claimed binding molecule.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D.

Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-7924.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

T. D. Wessendorf
Primary Examiner
Art Unit 1639

Tdw
January 12, 2004